OREGON LIQUOR & CANNABIS COMMISSION
CHAPTER 845
PROPOSED AMENDMENTS

Note: This draft of proposed amendments has been prepared for the Rules Advisory Committee scheduled for April 4, 2023 to discuss changes relating to artificially derived cannabinoids.

Division 25
RECREATIONAL MARIJUANA

845-025-1310
Artificially Derived Cannabinoids

(1) A licensee may transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid, including an artificially derived cannabinoid created by a refinement process using a reactive material such as bleaching clay, or a marijuana or hemp item that contains an artificially derived cannabinoid if:

(a) The artificially derived cannabinoid:

(A) Is not a controlled substance under OAR Chapter 855, Division 80;

(B) Was manufactured in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, and division 28;

(C) Was manufactured by a processor or an ODA Hemp Handler;

(D) In the Commission's judgment, is not impairing or intoxicating; and

(E) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications;

(b) The item is not intended for human inhalation; and

(c) The manufacturer of the artificially derived cannabinoid:

(A) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid and supplied a copy of that determination to the Commission;

(B) Has provided to the Commission a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(C) Has provided to the Commission an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

(2) The Commission will notify the licensee of acceptance of documentation received under paragraph (1)(c)(A), (B) or (C) of this rule and may apply additional labeling and concentration limit rules.

(3) Until ~~July~~ January ~~1~~2, ~~2023~~2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item containing the artificially derived cannabinoid cannabinol (CBN) if:

(a) The item is not intended for human inhalation; and

(b) The ~~artificially derived cannabinoid~~CBN:

(A) Is not a controlled substance under OAR Chapter 855, Division 80;

(B) Was manufactured in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, and division 28; ~~and~~

(C) Was manufactured by a processor or an ODA Hemp Handler; and

(D) Was manufactured by a person with written approval from the Commission affirming that the manufacturer:

(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(a) of this rule, including but not limited to initiating or contracting to initiate safety studies;

(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN and provided the Commission with a copy of the analysis; and

(iii) Has provided the Commission with copies of any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring a preventive control.

(4) A manufacturer may request written approval as described in subsection (3)(b)(C) of this rule in a form and manner prescribed by the Commission. The Commission:

(a) Shall publish a list of manufacturers who obtain this written approval.

(b) May revoke this approval if the manufacturer no longer meets the requirements described in subsection (3)(b)(C) of this rule. If the Commission revokes approval, the manufacturer has the right to a hearing under the procedures in ORS chapter 183.

(c) May consult with the Oregon Department of Agriculture for the purposes of reviewing the request.

(5) If the Commission requires a manufacturer to submit or produce documents to the Commission that the manufacturer believes falls within the definition of a trade secret as defined in ORS 192.501, the manufacturer must mark each document “confidential” or “trade secret.”

~~(4) Until July 1, 2022, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item containing artificially derived cannabinoids if:~~

~~(a) The artificially derived cannabinoids were manufactured by a processor or received by a licensee from a Commission-certified hemp handler before January 1, 2022;~~

~~(b) The manufacturing process did not involve treating a marijuana item or hemp item with an additive or substance that increased the potency; and~~

~~(c) The item otherwise complies with these rules.~~

(~~5~~6) A licensee may not transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid or a marijuana or hemp item that contains an artificially derived cannabinoid other than as provided in this rule.

(~~6~~7) The Commission may reevaluate the regulation of artificially derived cannabinoids on an annual basis, including establishing purity standards.

Statutory/Other Authority: ORS 475C.017
Statutes/Other Implemented: ORS 475C.017